

REMARKS

Claims 1-4, 8, 11-21, 23, 25 and 28-55 are pending in the above-reference application. Claims 1-4, 8, 11-21, 23, 25 and 28-55 are rejected in the final office action mailed on November 17, 2006.

Claims 56 and 57 have been added. Claims 1, 18, 34, 35, 36, 37, 47, 48, and 56 are the independent claims. Claims 1, 34, 35, 36, 37, 47 and 56 are directed to a system for clinical research data management. Claim 18, and 48 are directed to a method for clinical research data management.

Following the item numbering therein, the Office Action has:

In Items 2 and 3, rejected claims 1-4, 8, 11-21, 23, 25 and 28-55 under 35 USC 103(a) as being unpatentable over Rienhoff (US2003/0208454), in view of Fagan (US2003/0110058), in view of Bianco (US2002/0082865), and in view of Smirmiotopoulos (US 7,080,098).

More particularly, in regard to the independent claims, the Office Action has:

In Items 4, 16, 29, 30, 31, and 41, rejected claims 1, 18, 35, 36, 37, and 47, respectively, and over Rienhoff, Bianco, Fagan, and Smirmiotopoulos;

In Item 28, rejected claim 34 over Rienhoff and Bianco; and

In Item 42, rejected claim 48 over Rienhoff, Fagan, and Smirmiotopoulos.

Applicants have amended claim 1 to move the limitation "wherein the computer system is further operable to limit communication of electronic messages between users to those users having a specific role in connection with a specific study," to make the limitation more clear, and has amended claims 18, 34, 37, and 47 to add the limitation. The other independent claims have been amended to have a similar limitation. Applicants respectfully submit that none of the references alone or in combination teach or suggest the limitation that the computer system limits electronic messages based on a specific role that a user has in connection with a specific study.

The Office Action, has in regard to claim 1, alleged that Rienhoff teaches this limitation, citing page 4, paragraph 0044 of Reinhoff. However, the cited portion of Rienhoff does not teach that the system limits electronic messages based on roles. The cited portion teaches a method for developing trust by providing interviews or discussions with experts such as physicians, researcher, educators, nurses, counselors, or celebrities or public figures. This activity in Rienhoff is unrelated to the specific roles that may be assigned to personnel who use in the system of the present invention and says nothing about how those assigned roles would affect communication of messages within the system.

The Office Action has cited the same portion of Rienhoff in support of the rejection of claim 4, and claim 21, and cited FIG. 1, page 4, paragraph 0047 in support of the rejection of claim 35. Neither FIG. 1 nor Paragraph 0047 of Rienhoff supports this limitation. FIG. 1 is a simplified block diagram of the system in Rienhoff, showing among other items, one or more subscriber computers. Nothing about assigned roles in connection with a study is mentioned in the description of this figure. Rienhoff '454, paragraphs 0028-0037. Paragraph 0047 describes how a Website can provide subjects¹ with information regarding ongoing medical studies, again to gain the trust of the subject or to allow a subject to volunteer for a study. However, there is no mention of roles in the system or of communication within the system between personnel who use the system for clinical research based on their roles in connection with a specific study.

Furthermore, Smirniotopoulos does not teach this limitation either. While the Smirniotopoulos reference does mention the use of role-based schemes for access control to the system, Smirniotopoulos does not mention anything about communication within the system based on assigned roles in connection with a specific study.

Finally, the consultation process described in Smirniotopoulos, at Col. 6, line 63-Col. 7, line 20, does not meet the recited limitation "wherein the computer system is further operable to limit communication of electronic messages between users to those users having a specific role in connection with a specific study" of the present invention. The consultation process described provides that the database can send alerts to other registered users of the system by means of an automated solicitation service. The users can respond to the solicitation by logging on to the system and retrieve the case on which he or she will consult. The Smirniotopoulos reference thus describes a broadcast to find physicians who are interested in consulting on a particular case. Those who receive the message, therefore, have not been assigned a role in connection with a particular study. As Applicants' specification explains "No messages can be sent or received in connection with a given study unless the author and the recipient(s) have been assigned the proper role in connection with the study." Specification, page 20. Therefore, the Smirniotopoulos reference does not teach or suggest, alone or in combination, the limitation recited above.

Therefore, the independent claims are allowable over the proposed combination because the proposed combination fails to teach each and every limitation of the independent claims. Additionally, the dependent claims are allowable at least because they depend from the allowable

¹ Applicants note that the meaning of the word "user" in Rienhoff is not the same as the meaning of that term in the claims of the present invention. In Rienhoff, the word "user" means an individual who provides health information to the system. The word "user" in the claims refers to persons, such as medical personnel, who use the system for clinical research.

independent claims.

Regarding claims 2 and 19, the Office Action has cited paragraph 44 of Rienhoff as the basis of the rejection. However, the events referred to in claim 2 are not those in the cited portion of Rienhoff. The events in claim 2 are events contacts with medical personal. Such events include an initial visit, surgery and follow up visits. Applicants' Specification, page 22. The events referred to in Rienhoff refer to on-line events to gain the trust of a subject. Therefore, the cited portion of Rienhoff does not support the rejection.

Regarding claims 8 and 25, the Office Action has cited paragraph 41 of Rienhoff as the basis of the rejection. The cited portion only describes that users² of the web site may control the access rights to the information they submit to the web site in order to obtain or maintain the trust of the user. There is no mention of roles defining access rights at the dataset definition level or data item level. Therefore, the cited portion of Rienhoff does not support the rejection.

Regarding claims 11 and 28, the Office Action has cited paragraph 41 of Rienhoff as the basis of the rejection. However, the cited portion of Rienhoff does not describe that a role defines a user's capability to view privacy data. There is no mention of roles in the cited portion. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 16, the Office Action has cited paragraph 101 of Rienhoff as the basis of the rejection. However, the encryption referred to in the reference is not encryption of the data in the database, as recited in the claim. The cited portion of the reference only refers to encryption of data in a consent form obtained from a web site. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 23, the Office Action has cited paragraph 80 of Rienhoff as the basis of the rejection. However, the cited portion of the reference says nothing about roles and confuses the meaning of users in the reference with the meaning of users in the claims. See footnote 1. Therefore, the cited portion of the reference does not support the rejection.

Regarding claims 38 and 49, the Office Action has cited paragraph 46 of Rienhoff as the basis of the rejection. However, the users referred to in the reference are not the users of the system referred to in claim 37. See footnote 1. Therefore, the cited portion of the reference does not support the rejections.

Regarding claims 39-43, the Office Action has cited paragraph 129 of Rienhoff as the basis of the rejections. However, the cited portion of the reference says nothing about database

² See footnote 1.

tables, especially database tables that have fields associated with roles and events. Therefore, the cited portion of the reference does not support the rejections.

Regarding claim 44, the Office Action has cited paragraph 107 of Rienhoff as the basis of the rejection. However, the cited portion of the reference only refers to the types of samples that can be collected from a subject. The cited portion of the reference says nothing about the recording of an event in the database when an interaction with a study subject occurs. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 45, the Office Action has cited paragraph 69 of Rienhoff as the basis of the rejection. The cited portion of the reference describes types of queries on a questionnaire. The cited portion does not describe events as the term is used in the present invention, wherein events such as an initial visit, a surgery or a follow-up visit or treatment are stored in a table in the database. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 46, the Office Action has cited paragraph 108 of Rienhoff as the basis of the rejection. Paragraph 108 describes the process of analyzing samples. It does not state that the process is defined as an event which is recorded as such in the tables of the database. Furthermore, the cited portion does not describe scheduled or unscheduled events or events that are predefined or any status associated with an event for tracking purposes. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 49, the Office Action has cited paragraph 46 of Rienhoff as the basis of this rejection. However, paragraph 46 says nothing about maintaining an audit trail that records users' access information. Again the users in Rienhoff are being confused with the users of the present invention. See footnote 1. Claim 49 refers to the step of imposing role-based restrictions on user access. The cited portion of the reference says nothing about role-based restrictions on user access and nothing about whether this access information is recorded in an audit trail. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 50, the Office Action has cited paragraph 41 of Rienhoff as the basis of the rejection. Paragraph 41 does not address the user's access information as that term is used in the claims. Again, the Office Action confuses the meaning of the term user in Rienhoff with that of the present invention. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 51, the cited portion of the reference, paragraph 41 of Rienhoff, says nothing about whether the level of access is a dataset level or dataset item. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 53, the Office Action has cited paragraph 46 of Rienhoff as the basis of the rejection. However, paragraph 46 says nothing about how a capability can be mapped to a functional portion of the system. See Applicants' specification at page 30. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 54, the cited portion of the reference, paragraph 47 of Rienhoff, says nothing about the functional portions listed in the claim. Therefore, the cited portion of the reference does not support the rejection.

Regarding claim 55, the cited portion of the reference, paragraph 48, says nothing about deploying functional elements of the system for a clinical study and nothing about the functional elements of the system listed in claim 55. Therefore, the cited portion of the reference does not support the rejection.

In light of the above, Applicants believe that the proposed combinations do not teach or suggest the recited limitations of the independent and dependent claims. Thus, Applicants believe the claims are in condition for allowance which is respectfully requested.

Conclusion

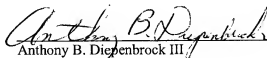
Claims 1-2, 8, 11-19, 23, 25, 28-51, and 53-57 are believed to satisfy all of the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly requested.

No fees beyond the RCE filing fee and extension of time fees are believed to be due in connection with this Amendment. However, the Director is authorized to charge any additional fees that may required, or credit any overpayment, to Dechert LLP Deposit Account No. 50-2778 (Order No. 369526-101 (346323)).

Respectfully submitted,

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